

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS
REPORTED IN D.D.N.J. 6041-6080

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopoeia), and its quality differed from the standard set forth in such compendium; Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from or its quality fell below that which it purported or was represented to possess; and Section 501(d)(2), the article was a drug, and a substance had been substituted wholly or in part therefor.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502(c), certain information required by the Act to appear on the label or labeling was not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug and (2) the drug was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use and (2) adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(i)(2), the article was an imitation of another drug and (3) the article was offered for sale under the name of another drug; Section 502(1), one article contained penicillin, one article contained chloramphenicol, and one article contained manganese bacitracin, and none of the articles were from a batch with respect to which a certificate or release had been issued pursuant to Section 507; and Section 503(b)(4), the article was subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

6041. Imitation Miltown tablets and imitation Equanil tablets. (F.D.C. No. 42166. S. No. 27-359 M.)

INDICTMENT FILED: 4-22-59, S. Dist. N.Y., against Seymour Blau, Ludwig Spandau, and Salude Laboratories, Inc., New York, N.Y.

ALLEGED VIOLATION: The indictment alleged that the defendants, with intent to defraud and mislead, caused to be introduced into interstate commerce, quantities of *imitation Miltown tablets* and *imitation Equanil tablets* containing meprobamate, which were new drugs and were adulterated and misbranded.

The indictment alleged also that from May 1, 1957 to the filing of the indictment the defendants did conspire, combine, confederate, and agree together and with other persons to violate 301(a) and 301(d) of the Act, and that it was a part of such conspiracy that the defendants, with intent to defraud and mislead, would unlawfully cause the above-mentioned tablets to be introduced into interstate commerce without effective new drug applications and in an adulterated and misbranded condition.

It was alleged further that in pursuance of the conspiracy and to effect the objects thereof the following overt acts were committed: that Ludwig Spandau, about July 1957, caused a number of *imitation Miltown tablets* and *imitation Equanil tablets* to be fabricated and to be packaged in unlabeled bottles and the bottles to be packed in cartons; that, on 7-30-57, Ludwig Spandau and Seymour Blau caused the tablets to be transported to the 34th St. Greyhound Bus Terminal, New York, N.Y.; that during the transportation of the tablets to the bus terminal, Seymour Blau affixed address stickers to the cartons; and that Seymour Blau delivered the tablets to the baggage room at the 34th St. Greyhound Bus Terminal.

CHARGE: 501(c)—when shipped, the quality of the tablets fell below that which they purported and were represented to possess since they contained less than 400 milligrams of meprobamate per tablet; 502(b)—the labels of the tablets failed to bear (1) the name and place of business of the manufacturer, packer, or distributor and (2) an accurate statement of the quantity of contents; 502(e)(1)—the labels of the tablets failed to bear the common or usual name of the drug; 502(f)(1)—the labeling of the tablets failed to bear adequate directions for use; 502(i)(2)—the tablets were imitations of other drugs, namely, Miltown and Equanil; 502(i)(3)—the articles were offered for sale under the name of other drugs, namely, Miltown and Equanil; and 503(b)(4)—the tablets were subject to 503(b)(1) and their labels failed to bear, prior to dispensing, the statement "Caution: Federal law prohibits dispensing without prescription"; and 505(a)—the articles were new drugs within the meaning of the law, and no applications were filed pursuant to 505.

PLEA: Guilty by Seymour Blau to all counts except those alleging the adulteration of the tablets and not guilty by the corporation and Ludwig Spandau to all counts.

DISPOSITION: On 8-3-59, the case against the corporation and Ludwig Spandau came on for trial before the court without a jury. The trial was concluded on 8-5-59, and at that time the court found Ludwig Spandau guilty and the corporation not guilty. On 9-9-59, Ludwig Spandau was given a suspended sentence of 6 months imprisonment and placed on probation for 1 year, and Seymour Blau was fined \$200 and placed on probation for 1 day.

6042. Meprobamate tablets. (F.D.C. No. 42475. S. Nos. 35-394 P, 35-397 P.)

INFORMATION FILED: 10-9-59, E. Dist. Pa., against Jan Laboratories, Philadelphia, Pa., a partnership, Jerry Levin, a partner in the partnership, and Edward Lavin, a salesman for the partnership.

ALLEGED VIOLATION: The information alleged that, on 4-29-58, while a number of *meprobamate tablets* were being held for sale after shipment in interstate commerce, Jan Laboratories and Jerry Levin caused a number of the tablets to be repacked into a bottle and did sell and dispose of the bottle at Philadelphia, Pa., which acts of causing the repacking, sale, and disposal resulted in the drug being misbranded within the meaning of 502(a).